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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,895	03/06/2000	Kalyan Handique	UM-04228	8654

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EXAMINER

LUDLOW, JAN M

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 07/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/518,895

Applicant(s)

HANDIQUE ET AL

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/9/03
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,6,8 and 10-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,8 and 10-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Claims 1, 3, 5-6, 8, 10-13 are objected to because of the following informalities: In claims 1 and 6, "said gas vent" lacks antecedence. For purposes of examination, the claims have been treated as positively reciting a gas vent. Claims 3 and 5 depend from cancelled claim 2. For purposes of examination, they are treated as being dependent from claim 1. Claim 3 is redundant with claim 1 as interpreted above. Claims 8 and 11 depend from cancelled claim 7. For purposes of examination, they are treated as being dependent from claim 6. Appropriate correction is required.

2. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 8, "a vent" is unclear because it is unclear whether the vent of claim 6 is intended or an additional vent is intended.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C.

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122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1. Claims 1, 3, 5-6, 8, 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al (5922591).

Note that the claims have an effective filing date of 9/26/1997.

Anderson teaches a microfluidic device made by, e.g., etching a silicon or glass substrate (col. 18, lines 60-62). Channels are typically 10 to 1000 um wide and 1 to 500 um deep, which range overlaps the claimed range (col. 18, lines 39-40). A porous hydrophobic portion may be provided in a channel intermediate an inlet and a vent to provide debubbling (col. 30, lines 1-25, figure 12B). Positive pressure may be applied to the inlet (e.g., col. 30, lines 43-44) and pressure is exemplified by gas pressure (col. 27, lines 23-24). Any volume holding the pressurizing gas constitutes the instant air chamber. With respect to claim 6, port 1280 constitutes the first end/liquid inlet, port 1278 constitutes the gas inlet, region 1254 has the hydrophobic region/vent intermediate to second end/gas vent 1270.

2. Alternatively, claims 1, 3, 5-6, 8, 10-13 are rejected under 35 U.S.C. 103 as being obvious over Anderson et al (5922591).

Note that the claims have an effective filing date of 9/26/1997.

Anderson teaches a microfluidic device made by, e.g., etching a silicon or glass substrate (col. 18, lines 60-62). Channels are typically 10 to 1000 um wide and 1 to 500 um deep, which range overlaps the claimed range (col. 18, lines 39-40). A porous hydrophobic portion may be provided in a channel intermediate an inlet and a vent to provide debubbling (col. 30, lines 1-25,

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figure 12B). Positive pressure may be applied to the inlet (e.g., col. 30, lines 43-44) and pressure is exemplified by gas pressure (col. 27, lines 23-24).

Anderson fails to teach a specific embodiment using gas pressure at an inlet port of a device as shown in Figure 12C incorporating the alternative debubbling chamber of Figure 12B.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the debubbler of Figure 12B in the device of Figure 12C and gas pressure as the positive pressure in order to incorporate the alternative features taught by Anderson for the purposes taught by Anderson in the device of Anderson. Any volume holding the pressurizing gas constitutes the instant air chamber. With respect to claim 6, port 1280 constitutes the first end/liquid inlet, port 1278 constitutes the gas inlet, region 1254 has the hydrophobic region/vent intermediate to second end/gas vent 1270.

3. Claims 1, 3, 5-6, 8, 10-13 are rejected under 35 U.S.C. 103 as being obvious over Mian et al (6319469).

Note that claims 1, 3, 5-6, 8, 10-13 have an effective filing date of 9/26/1997.

Mian teaches a microfluidic device made from, e.g., etched glass or silicon (col. 4, lines 9-15). Air inlets, outlets (instant vents) and holding chambers are provided in the channels to direct movement of the fluid (col. 8, lines 54-end). Microchannel sizes may be from 0.1 μm to close to 1mm (col. 8, line 38). Hydrophobic portions may be provided to bind cells or other reagents (col. 14, line 45 to col. 15, line 15).

It would have been obvious to provide a hydrophobic region in the channels of Mian in order to bind desired reagents as taught at a position between the inlet and outlet for passing fluid over the reagents using pressure differentials as taught. It would have been obvious to make the

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channels of the claimed width in order to be proportionate to the depth disclosed. Note that there are no structural features claimed defining a microdroplet channel over any other microfluidic channel. With respect to “air inlets”, once liquid has been applied to the inlet and moved by motion of the rotor, the fluid moving through the channel inherently creates a vacuum behind it and air will flow into the channel from the atmosphere. Even if no vacuum is created, an inlet not occupied by liquid (once moved by rotor motion) and open to atmosphere will fill with air. Further, the examiner notes there is no claimed structural difference between an air inlet and a liquid inlet. The Figures show plural embodiments with ports intermediate the channel ends, the ports structurally capable of admitting air once liquid moves from the port through the channel.

4. Applicant's arguments filed April 9, 2003 have been fully considered but they are not persuasive.

5. With respect to Anderson, applicant argues that the vent of Anderson is hydrophobic, not a region of the channel. In that the vent shown in the middle of the channel of figure 12B has a surface constituting the channel wall, that hydrophobic surface is a region of the channel. There is no limitation in the claim requiring the hydrophobic region to be non-porous. Applicant even acknowledges that the vent is “**incorporated** into [the] channel”; therefore the channel comprises the vent. Clearly, applicant must agree with the examiner that the hydrophobic membrane is part of the channel.

Applicant argues that the examiner attempted to “create” a gas inlet and has improperly integrated disparate discussions of the “pressure differential transport system” and “the fluid inlet system”. The examiner has done no such thing. “Fluid” indicates a gas or liquid and the disclosure indicates that gas pressure may be applied to the fluid inlet port. Applicant has even

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kindly quoted a portion of the text supporting the examiner's position: "Application of a **positive pressure to the fluid inlet port...**" The positive pressure may be gas pressure, so the combination of these teachings is application of a gas pressure to the fluid inlet port. When gas pressure is connected to the fluid inlet port, gas inherently enters the channel. Thus, the fluid inlet port is a gas inlet port (as well as a liquid inlet port). The examiner didn't "create" the gas inlet port, Anderson did. The examiner further notes that with respect to Figure 12B, Anderson teaches gas bubbles purposely introduced into the device between the liquid aliquots, which are introduced through the fluid inlet port (col. 30, line 14). Further, the examiner notes there is no claimed structural difference between an air inlet and a liquid inlet. With respect to the vacuum source, vacuum is taught as an alternative or adjunct to the pressure source and does not negate the teaching of the application of gas pressure to move the liquid sample (col. 30, line 53).

With respect to Mian, applicant's arguments are not persuasive because once liquid has been applied to the inlet and moved by motion of the rotor, the fluid moving through the channel inherently creates a vacuum behind it and air will flow into the channel from the atmosphere. Even if no vacuum is created, an inlet not occupied by liquid (once moved by rotor motion) and open to atmosphere will fill with air. Further, the examiner notes there is no claimed structural difference between an air inlet and a liquid inlet. Applicant alleges that the fluid inlets do not allow air entry, but has provided no logical reasoning as to why this is so. Given the examiner's well-reasoned explanation, applicant clearly now understands that the inlets taught by Main do permit air entry.

Applicant argues that Main does not teach fluid movement driven by differential gas pressures. This argument is irrelevant because the instant claims are not so limited.

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6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

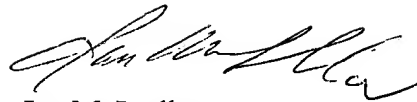
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

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Jan M. Ludlow
Primary Examiner
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jml

June 30, 2003